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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,637	04/13/2001	Yoshikatsu Kodama	011900-309	3072

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/02/2003

93

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,637

Applicant(s)

KODAMA ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-30 is/are allowed.
- 6) ☒ Claim(s) 16 and 22-26 is/are rejected.
- 7) ☒ Claim(s) 17-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of the Claims

1. Claims 12-30 are pending.

Applicants' amendment filed on January 22, 2003 (Paper No. 11) is acknowledged.

Applicants' response has been fully considered. Claim 22 has been amended, and claims 12-15 stand withdrawn from consideration. Therefore, claims 16-30 are examined.

2. A copy of Japanese Application 2000-113913 filed February 7, 2003 is acknowledged.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claim 22, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 4 in Paper No. 11.

4. The previous rejection of claims 17-21, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' response at page 4 in Paper No. 11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 16 and 22-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Peterson *et al.* (U. S. Patent 5,505,955).

Art Unit: 1653

Peterson *et al.* teach a glycoprotein, which has a molecular weight of 46 kDa and is isolated upon fractionation of human milk fat globules (column 5, lines 23-35; Example 7), absent factual data to the contrary, is the claimed glycoprotein and has the inherent property of the claimed glycoprotein (claim 16). Therefore, chicken egg or milk is anticipated as a food (claim 24) and a pharmaceutical composition (claim 23) which have the property of the glycoprotein, and as an inhibitor of *Helicobacter pylori* colonization (claim 22). Chicken egg or milk also contains fat which is an inhibitor of gastric acid secretion, therefore chicken egg or milk is anticipated as an inhibitor composition of *Helicobacter pylori* colonization (claim 25) and a pharmaceutical composition (claim 26) which contain the properties of the glycoprotein and fat.

In response, applicants indicate the glycoprotein of the present invention, which is derived from milk whey and contains mainly sulfated components (Exhibit A), masked the adhesion of *Helicobacter pylori* urease and exhibits remarkable effects on the inhibition of *Helicobacter pylori* urease adherence mucosa, thus inhibiting *Helicobacter pylori* colonization in the stomach; while the glycoprotein disclosed in the patent 5,505,955 is derived from milk fat globules (MFG) and contains primarily sialylated components, this glycoprotein does not specifically bind to *Helicobacter pylori* urease, which is indicated by the high IC_{50} values (324-397 $\mu\text{g/ml}$) as compared to those (3.9-4.5 $\mu\text{g/ml}$) of glycoprotein from bovine milk whey (pages 4-7 of the response; Table 1 of Exhibit A). Applicants' response has been fully considered, however, the argument is not found persuasive because neither the specification nor the claim defines the term "specifically binds", thus, the glycoprotein of patent 5,505,955 although binds *Helicobacter pylori* urease weakly, it cannot be differentiated from the glycoprotein of the instant

Art Unit: 1653

invention since the specific properties of the glycoproteins of the present invention and the source of the glycoprotein isolated from, which are indicated by applicants, are not cited in the claim.

6. Claims 17-21 are objected to because the claim depends from a rejected claim, claim 16.

Conclusion

7. Claims 16 and 22-26 are rejected, and claims 17-21 are objected. It appears claims 27-30 are free of prior art.

Art of Record

Chick egg or milk contains the glycoprotein which binds to urease of *Helicobacter pylori*, inhibits the adherence of urease to gastric mucosa, and eliminate colonized *Helicobacter pylori* in the stomach because the specification indicates the glycoprotein is obtained from milk of a cow or albumen of a chicken egg (page 3, line 25-page 4, line 6). Hashimoto *et al.* (Digestive Disease and Sciences, 36, 888-892 (1991) teach fat is an inhibitor of gastric acid secretion (page 889, right column; page 890, left column; Fig 1).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1653

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 26, 2003

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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